COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
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WWW.COOKMEDICAL.COM

JUL 17 2013

510(k) Summary
Date prepared: June 14, 2013

Submitted By: David Lehr, RAC, Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
Phone: (812)339-2235 Ex. 2309 Fax: (812)332-0281

Device:
Trade Name: Roadrunner® UniGlide™ Hydrophilic Wire Guide
Common Name: Guide Wire, Catheter
Proposed Classification: DQX (21 C.F.R. § 870.1330)

Indications for Use:

For use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Predicate Device:

Roadrunner® UniGlide™ Hydrophilic Wire Guide, K110009, February 2, 2011

Device Description:

The Roadrunner® UniGlide™ Hydrophilic Wire Guide is a hydrophilically coated device constructed of a nitinol core wire with a polyurethane jacket. It is available in diameters ranging from 0.018 in. to 0.038 in. and lengths from 80 cm to 320 cm. The Roadrunner® UniGlide™ Hydrophilic Wire Guide is manufactured in both a standard shaft and a stiff shaft version. A torque device is supplied with the Roadrunner® UniGlide™ Hydrophilic Wire Guide. The torque device is designed for torque control and is intended for use in complex diagnostic and interventional procedures.

Substantial Equivalence:

The Roadrunner® UniGlide™ Hydrophilic Wire Guide proposed in this submission is substantially equivalent to the Roadrunner® UniGlide™ Hydrophilic Wire Guide (K110009), which is currently marketed by Cook Incorporated. The proposed Roadrunner® UniGlide™ Hydrophilic Wire Guide has indications for use, materials of construction, and technological characteristics identical to those of the predicate Roadrunner® UniGlide™ Hydrophilic Wire Guide.

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Comparison to Predicate Device:

The Roadrunner® UniGlide™ Hydrophilic Wire Guide has been modified from the predicate Roadrunner® UniGlide™ Hydrophilic Wire Guide to include additional device lengths of 260 and 320 cm. The proposed Roadrunner® UniGlide™ Hydrophilic Wire Guide is comparable to the predicate device in design, intended use, materials, and technology.

Test Data:

The Roadrunner® UniGlide™ Hydrophilic Wire Guide was subjected to the following test to assure device performance and to assure that the design modification of the device is reliable under the specified testing parameters.

Hydrated Lubricity Test: This testing confirmed that the hydrated lubricity for the modified 260 cm and 320 cm wire guides is equivalent to the hydrated lubricity demonstrated by the predicate wire guides.

In conclusion, the results of testing provide reasonable assurance that the device is as safe and as effective as the predicate device, and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 17, 2013

Cook, Inc.
c/o Mr. David Lehr, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K130766
Trade/Device Name: Roadrunner® UniGlide™ Hydrophilic Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II
Product Code: DQX
Dated: June 14, 2013
Received: June 18, 2013

Dear Mr. Lehr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): _____

Device Name: Roadrunner® UniGlide™ Hydrophilic Wire Guide

Indications for Use:

For use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Prescription Use __X___	OR	Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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